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Hearing on
"Project BioShield: Linking Bioterrorism Threats and Countermeasure Procurement to Enhance Terrorism Preparedness"

Mr. Chairman, Members of the Committee: I commend this committee for its focus on the vital legislation which brings us together today.

I am David Wright, President and CEO of PharmAthene.

PharmAthene was founded to develop countermeasures for bioterrorism and has made significant progress in developing products which prevent and treat anthrax and agents of chemical warfare. In two short years, we have brought two products forward to a stage where they could soon be acquired for the Strategic National Stockpile.

PharmAthene has had experience with Project BioShield, DHHS, DOD, and indirectly DHS in developing our products. Our lead product, Valortim™, which we are co-developing with Medarex based in New Jersey, has demonstrated significant efficacy in preventing and treating anthrax and is poised to become an important component of the U.S arsenal to combat this dire threat. Our second product, Protexia™, an effective countermeasure against chemical and nerve agents, has gained critical support from DOD, which has a strong interest in developing and procuring effective nerve agent antidotes to protect the war fighter. PharmAthene has invested in these technologies because the USG clearly communicated it was seeking effective countermeasures in the anthrax and chemical areas.

As a company devoted to the area of biological and chemical defense we have made a great start in a short amount of time. However, it is difficult to determine where we should go next, or to substantiate potential acquisitions or investments to my board, because the current procurement process is cumbersome from two principal vantage points: 1) it is not transparent and 2) it does not provide sufficient information about future countermeasure needs. It costs over $150 million to bring a new biodefense drug to the market and a typical drug development program takes 4-6 years. Companies, particularly small biotechnology companies like PharmAthene, cannot afford to make these types of investments unless they believe there is a real and sustainable market for their products.

DHS plays a critical role in determining what constitutes a material threat and what the scope of that threat is. It is this role, and how the material threat assessment (MTA) process, which

culminates in an actual requirement for SNS procurement, affects biodefense companies like mine, that I would like to discuss this morning. These include:

1) Transparency – identifying the government's countermeasure needs early enough for companies to make informed decisions
2) The Requirements Process – creating a more coordinated, less burdensome, and timely requirements process, and
3) BioShield Funding – ensuring adequate funds are made available to support the nation's biological and chemical defense needs

In order to be successful, the Project BioShield procurement process must be more transparent. I believe Department officials and industry must work together to develop ways to integrate industry into countermeasure decision making sooner. The DOD process is a good one to review here, as DOD has a lot of experience developing complex weapons systems and involving industry early. Our Protexia product has certainly benefited from the DOD approach. DOD identifies capability needs for the near-term, mid-term and long-term and fully funds these programs. These capability needs are shared with industry and several times a year, DOD officials meet with industry to outline their needs and seek partners. Further, once a promising technology is identified, funding is available to support development across the complete development spectrum through the tech base, Milestone A and Milestone B process. Project BioShield would attract more interest and investment from industry if it employed similar techniques.

With regard to the requirements process, much can be done to expedite the process and better communicate the results. The current process is complicated and disjointed. Before DHHS can actually procure a countermeasure for stockpile, a number of activities must occur – DHS must complete an MTA, which can take from several months to several years, DHHS must determine there is a need for new countermeasures, and the many members of the Weapons of Mass Destruction – Medical Countermeasures group must agree on a requirement. In addition, to DHS and DHHS, many other agencies and Departments are involved in this process including DOD, OMB, and the intelligence community. It is unclear who or which department or agency has ultimate decision making authority. Plus, with so many chefs in the kitchen the time needed to reach agreement is substantially lengthened delaying procurement decisions.

A second issue is, what appears to be, a tenuous link between the original threats analysis and the actual SNS requirement. Last year, PharmAthene responded to an RFP that requested offerors to bid on providing anywhere from 10,000 treatments to 200,000 treatments. Ten thousand treatments or even 20,000 treatments are not a market any company can afford to consider. It is not reasonable to expect companies to invest millions of dollars in a technology for such a small order. If the original MTA indicated only a very limited exposure resulting in a limited SNS requirement, companies need this information up front to evaluate program opportunities and inform decision making. Furthermore, the cost to the U.S. government would be prohibitive on a per dose basis. If, on the other hand, a much larger requirement is warranted based on the MTA and DHHS assessments, but the resulting RFP does not reflect the real need, there is a disconnect in the requirements process. We would hope that given the importance of developing countermeasures to protect the nation, that as part of your deliberations on BioShield II, the

committee would consider mechanisms to both streamline the requirements process and communicate early and clearly the government's procurement intentions (what, when, how much).

Finally, I would like to note one other issue that we believe is critical in your consideration of BioShield II - funding. Congress has taken the first step in combating biological and chemical terrorism by setting aside $5.6 billion for SNS procurement. This is a good first step. Yet it is insufficient to support the breadth of technologies needed to protect this nation. To be effective, MTAs should take into account not only the likely exposure estimate but also the long-term effects of a biological or chemical attack. A realistic anthrax scenario, for example, must address not only the morbidity and mortality of the exposed population, but also take into account how the geographic area will be impacted. Anthrax can exist in the soil for over 30 years. The resources necessary to make the area inhabitable again will be enormous. Threat analyses should not be limited to what can be accomplished with current funding, but should be devised separately from fiscal constraints. While industry recognizes that funds in this area are not limitless, a process that begins with estimates based on unrealistic scenarios or developed to meet a certain fiscal end, will not only discourage companies from entering this market, but also leave our country woefully unprotected.

Thank you for the opportunity to share my views on BioShield II with you today. I believe BioShield II can be a powerful incentive to companies in the biodefense space, and urge you to include important provisions enhancing transparency, streamlining the requirements process and authorizing additional funds as necessary. Doing so, will go a long way toward ensuring that the USG can procure the products it needs to protect the American people.

I would be pleased to address any questions the Committee may have at this time. Thank you.